Provisional Patent Applications –
A Panacea for Large and Small Molecules?
March 15, 2023

Provisional Patent Applications – A Panacea for Large and Small Molecules?

Short Answer – No

Long Answer - Maybe

Speakers

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Overview

- Basics regarding provisional patent applications
- Provisional positives
- Provisional pitfalls
- Using provisionals effectively

Basics – Provisional Applications

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Transforming Ideas into Opportunities

Differences between Provisional and Non-Provisional Applications

Provisional

- No substantive examination
- Does not issue as a patent (expires after 12 months)
- No claims required
- Cheaper to file
- Does not detract from term
- Cannot claim priority
- Does not publish (but publicly available when non-provisional claiming priority to it publishes)
- Can mark invention "patent pending"
- Protects absolute novelty

Non-provisional

- Examined
- Will issue as patent or go abandoned
- Claim(s) required
- More fees/more formalities
- Starts 20-year term clock
- Can claim priority to provisional and non-provisional applications
- Published 18 months after first effective filing date (unless will not file in other countries and request non-publication)
- Can mark invention "patent pending"
- Protects absolute novelty

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Filing Requirements For Provisional and Non-Provisional

Complete Provisional Application

- Cover Sheet
  - Identifying as provisional
  - Title
  - Inventor information (can be "John Doe" inventor, city and state)
  - Federal Funding
- Specification
- Drawing(s), if necessary
- Fees

Complete Non-provisional Application

- Specification
  - At least one claim
- Drawing(s), if necessary
- Inventor's Declaration*
- Fees*

(Federal funding identified in body of application)

* Can be filed late with additional fees

Filing Strategies (examples)

1. Provisional(s) → PCT (± non-PCT countries) → PCT Regional/National Stages US, CA, EP, AU, etc.

AND/OR

→ Direct non-provisional (e.g., US)

2. Non-provisional (e.g., US) → PCT (± non-PCT countries) → PCT Regional/National Stages US, EP, AU, etc.

OR

Direct non-provisional (e.g., EP)

Provisional Positives

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Patent Term for Utility Applications

Term
- 20 years from the filing date of the application (provisional does not count against term)

Patent Term Adjustment
- USPTO must meet certain deadlines
- Counterbalanced by applicant delay

Patent Term Extension
- Drug products and medical devices (max 5 years to term and max 14 years from approval)

Terminal Disclaimers

Payment of Maintenance Fees

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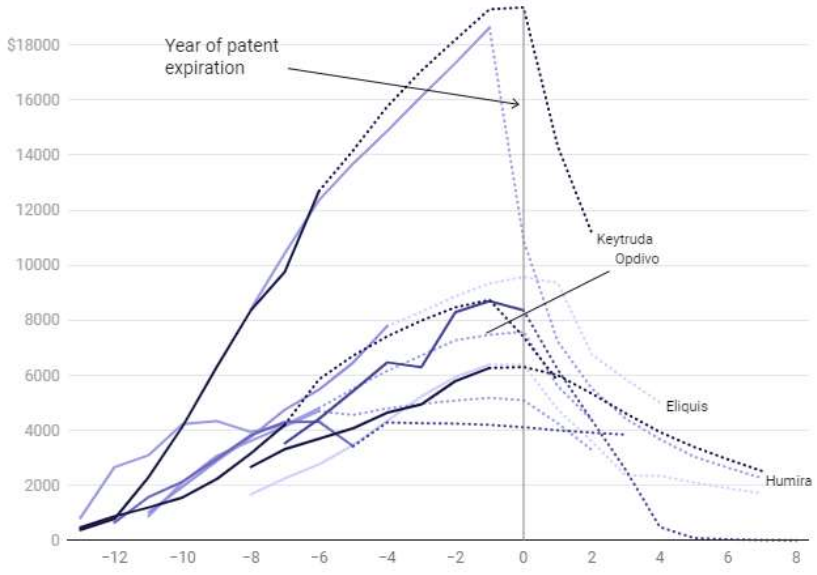
Criticality of the Last Year of Patent Term



Solid lines represent actual revenue, through 2021. Dotted lines represent projected revenue. Numbers in millions USD.

Chart: Julia Himmel / BioPharma Dive • Source: Companies, Evaluate Pharma • Created with Datawrapper

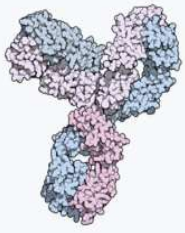
Note:

1) Price after patent expiry
2) Increase in revenue over patent term

Large Molecules/Small Molecules

Exemplary Biologic - Keytruda

Pembrolizumab

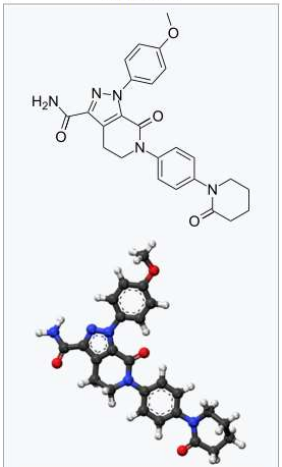


From PDB entry 5dk3

Monoclonal antibody	
Type	Whole antibody
Source	Humanized (from mouse)
Target	PD-1
Clinical data	
Trade names	Keytruda

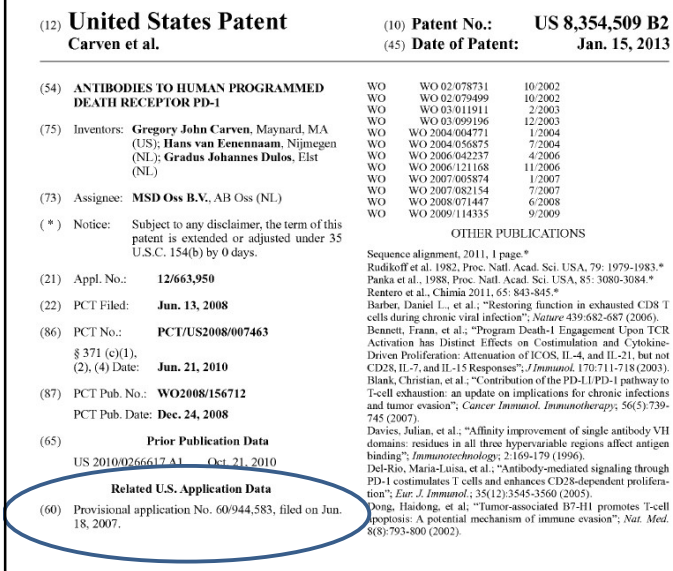
Exemplary Small Molecule - Eliquis

Apixaban



Clinical data	
Trade names	Eliquis, others

Exemplary Keytruda Patent



(12) **United States Patent**
Carven et al.

(10) **Patent No.: US 8,354,509 B2**
(45) **Date of Patent: Jan. 15, 2013**

(54) **ANTIBODIES TO HUMAN PROGRAMMED DEATH RECEPTOR PD-1**

(75) Inventors: **Gregory John Carven**, Maynard, MA (US); **Hans van Eenennaam**, Nijmegen (NL); **Gradus Johannes Dulos**, Elst (NL)

(73) Assignee: **MSD Oss B.V.**, AB Oss (NL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **12/663,950**

(22) PCT Filed: **Jun. 13, 2008**

(86) PCT No.: **PCT/US2008/007463**
§ 371 (c)(1),
(2), (4) Date: **Jun. 21, 2010**

(87) PCT Pub. No.: **WO2008/156712**
PCT Pub. Date: **Dec. 24, 2008**

(65) **Prior Publication Data**
US 2010/0266617 A1 Oct. 21, 2010

Related U.S. Application Data
(60) Provisional application No. 60/944,583, filed on Jun. 18, 2007.

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WO	WO 2006/121168	11/2006	
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Blank, Christian, et al.; "Contribution of the PD-L1/PD-1 pathway to T-cell exhaustion: an update on implications for chronic infections and tumor evasion"; *Cancer Immunol. Immunotherapy*; 56(5):739-745 (2007).
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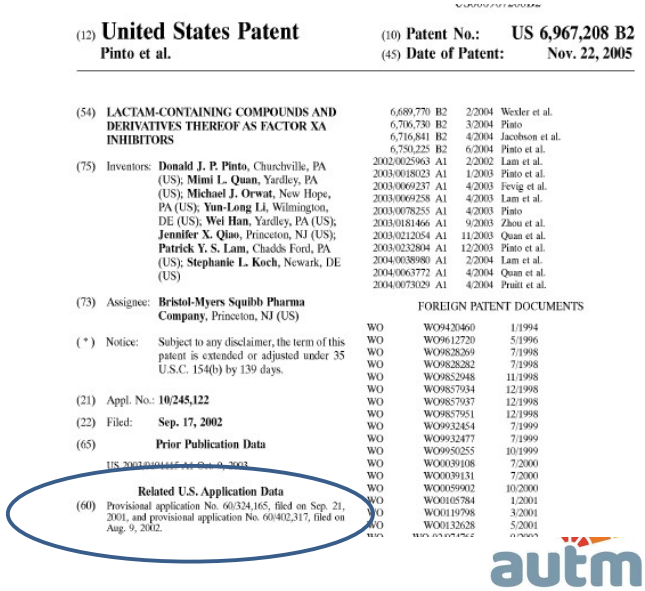
Del-Rio, Maria-Luisa, et al.; "Antibody-mediated signaling through PD-1 costimulates T cells and enhances CD28-dependent proliferation"; *Eur. J. Immunol.*; 35(12):3545-3560 (2005).
Dong, Haidong, et al; "Tumor-associated B7-H1 promotes T-cell apoptosis: A potential mechanism of immune evasion"; *Nat. Med.* 8(8):793-800 (2002).

Exemplary Eliquis Patent



(12) **United States Patent**
Pinto et al.

(10) **Patent No.: US 6,967,208 B2**
(45) **Date of Patent: Nov. 22, 2005**

(54) **LACTAM-CONTAINING COMPOUNDS AND DERIVATIVES THEREOF AS FACTOR XA INHIBITORS**

(75) Inventors: **Donald J. P. Pinto**, Churchville, PA (US); **Mimi L. Quan**, Yardley, PA (US); **Michael J. Orwat**, New Hope, PA (US); **Yun-Long Li**, Wilmington, DE (US); **Wei Han**, Yardley, PA (US); **Jennifer X. Qiao**, Princeton, NJ (US); **Patrick Y. S. Lam**, Chadds Ford, PA (US); **Stephanie L. Koch**, Newark, DE (US)

(73) Assignee: **Bristol-Myers Squibb Pharma Company**, Princeton, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 139 days.

(21) Appl. No.: **10/245,122**

(22) Filed: **Sep. 17, 2002**

(65) **Prior Publication Data**
US 2003/0191145 A1 Oct. 9, 2003

Related U.S. Application Data
(60) Provisional application No. 60/324,165, filed on Sep. 21, 2001, and provisional application No. 60/402,317, filed on Aug. 9, 2002.

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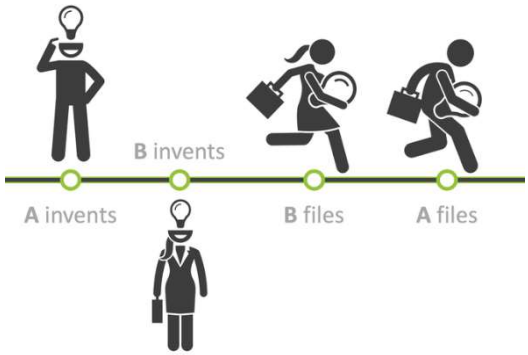
Opportunity to Add New Developments

Provisional application cannot itself be amended but additional provisionals or non-provisionals claiming priority to the provisional can include more

- Identification of lead large/small molecule
- New large/small molecules
- New data
- New uses
- New methods of making

First to File



America Invents Act (AIA)

Effective March 16, 2013, the US changed from first-to-invent to first-to-file

- Before the effective date of the AIA – A should win if diligent in developing of and filing on the invention
- After the effective date of the AIA – B should win as first to file

Filing early in a rapidly developing field is important

Delay

1. Provisional(s) → PCT → PCT Regional/National Stages US, CA, EP, AU, etc.

Provisional offers a delay in costs

- Can postpone national stage filings for 30-31 months (even up to 42 months in CA)

Provisional offers a delay in formalities

- Analysis of inventorship/ownership

Provisional offers a relatively low-cost year in which to seek a licensee

Reasons to File a Provisional to Protect Large/Small Molecules

Commercial importance of last year of term

First to file – allows for quick filing to establish filing date

Allows for modification through serial provisionals and/or additions to non-provisional

Delay – costs, details

BUT . . .

Provisional Pitfalls

Establishing a Priority Date

Priority to a provisional is limited to the disclosure within the provisional(s)

- The invention of some claims in the non-provisional may be disclosed in the earliest provisional
- The invention of other claims in the non-provisional may be disclosed in second (or subsequent) provisional
- The invention of yet other claims in the non-provisional may not be disclosed in the provisional(s)

(Different claims can have different priority dates)

Large/small molecules generally considered unpredictable sciences

- Requires chemical compounds or sequences for written description
- Requires multiple examples to establish a genus (issue before Supreme Court now regarding antibody claims)
- Requires methods of making/using and data

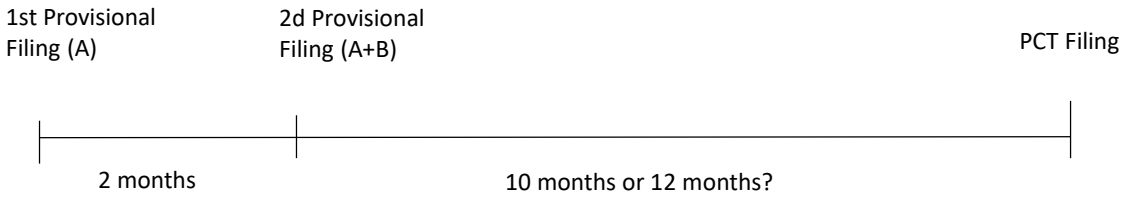
Coversheet provisionals can give a false sense of security

Intervening Public Disclosures

If P1 discloses only A, P2 discloses A+B, and intervening publication discloses A+B

- If publication by inventors, no priority to P1 for B
- If publication by a third party, could be prior art for B

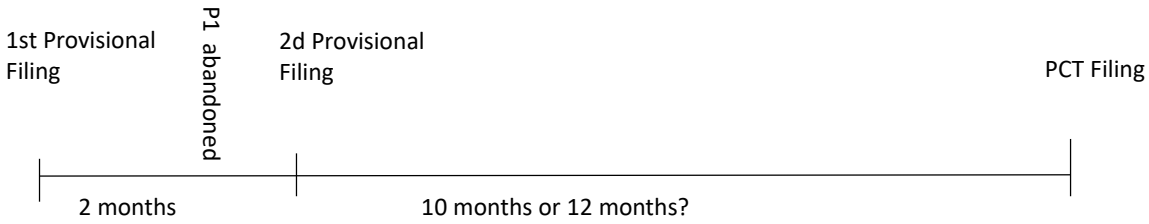
Right to Claim Priority



Can client claim priority only to P2 and file 12 months from that date?

The client can claim valid priority from P2, but only for claims that rely on subject matter NOT in P1 (B)
unless . . .

Right to Claim Priority (continued)



". . . the said previous application has been withdrawn, abandoned, or refused, without having been laid open to public inspection and without leaving any rights outstanding. . ."

Exception – if P1 is expressly abandoned BEFORE P2 filed, then P2 can serve as the earliest filed application

Provisional as Prior Art

P1 is publicly available when the non-provisional application publishes

- If P1 discloses A+B, but non-provisional discloses and enables only A, P1 can be prior art as to subsequent inventions related to B
- Could file ON THE SAME DAY multiple provisionals of varying scope and select at "conversion" which serves as priority document - avoid creating art as to your later inventions

Informalities from Provisional Might Persist

Inventorship – should be evaluated at time of filing provisional or non-provisional and re-evaluated whenever claims change

Ownership - assignments should be secured from all inventors prior to filing a PCT or in the EP listing the university as sole applicant

Summary of Provisional Pitfalls

- Priority date of claims only applies to what is disclosed in the provisional – different claims in a non-provisional can have different priority dates
- Large and small molecules require detailed specification for enablement/written description
- Public disclosure after a provisional could exceed the scope of the provisional
- Cannot generally roll your final deadline for claiming priority to a series of provisionals – unless you have abandoned provisional before filing the next one
- Provisional becomes publicly available when non-provisional claiming priority publishes
- Informalities can carry over into non-provisional

Take-Home Message: Provisional Strategy

- Use provisionals to maximize profits - last year of patent term often critical for large/small molecules
- File fully enabled specifications
- Attend to formalities (claims, sequence listings, drawings, inventorship, ownership) before 12-month deadline
- File multiple provisionals as needed – consider abandoning first provisional before a second provisional is filed
- Limit public disclosures to what is in the filed provisionals
- Limit priority claims to the “first filed application not otherwise abandoned leaving no rights outstanding”
- Include grant support in the provisional and disclose to granting agency